June 7, 2022

ReShape Lifesciences
Michelle Ravert
Sr. Regulatory Specialist
1001 Calle Amanecer
San Clemente, CA 92673

Re: K220455
Trade/Device Name: Lap-Band System Calibration Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: March 8, 2022
Received: March 10, 2022

Dear Michelle Ravert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Je Hi An, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220455

Device Name
LAP-BAND® System Calibration Tube

Indications for Use *(Describe)*
The LAP-BAND® System Calibration Tube is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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ReShape Lifesciences™

510(k) Summary

I. Basic Information

510(k) Owner	ReShape Lifesciences 1001 Calle Amanecer San Clemente CA 92673 Phone: (844) 937-7374 Establishment Registration No: 3013508647
Contact Person	Michelle Ravert, Regulatory Affairs Manager
Date summary Prepared	June 06, 2022
Trade Name	Lap-Band® System Calibration Tube
Common Name	Introduction/Drainage Catheter
Classification	Class II, KNT
Predicate Device	ReShape Lifesciences Gastric Balloon Suction Catheter, K002838

II. DEVICE DESCRIPTION

The Lap-Band® System Calibration Tube is a flexible gastric tube designed to be used in gastric and bariatric surgical procedures. The catheter provides visible and tactile delineation of the antrum of the stomach along with the ability to decompress the stomach, drain and remove gastric fluid and size a gastric pouch.

The dual lumen Calibration Tube utilizes one lumen for drainage, suction and irrigation and the second lumen to inflate/deflate the balloon. The catheter is attached to a 32-inch suction tubing and a 6-inch tubing with a stopcock for filling the balloon.

III. INDICATIONS FOR USE

The Lap-Band® System Calibration Tube is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch.

IV. BASIS FOR SUBSTANTIAL EQUIVALENCE

Substantial equivalence of the Lap-Band® System Calibration Tube to the predicate device (Gastric Balloon Suction Catheter, K002838) was established through an evaluation of the indications for use, principle of operation, device design, materials of construction, and an assessment of usability, safety, and effectiveness via bench and animal studies.

The data presented in this summary demonstrates the technological similarity and equivalency of the Lap-Band® System Calibration Tube to the predicate device (Gastric Balloon Suction Catheter K002838).

The devices:

- have the same intended use,
- use the same principle of operation,
- incorporate the same basic design,
- use similar construction and material, and
- are provided non-sterile and packaged using the same processes.

In summary, the Lap-Band® System Calibration Tube described in this submission is substantially equivalent to the predicate device (Gastric Balloon Suction Catheter K002838).

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the Lap-Band® System Calibration Tube and the predicate device (Gastric Balloon Suction Catheter K002838) is provided in **Table 1**.

Table 1: Comparison of Subject Device and Predicate Device

Feature	**Predicate Device** **Gastric Balloon Suction Catheter** **K002838**	**Subject Device** **Calibration Tube**	**Effect on Substantial Equivalence**
Product Code	KNT	Same	None
Regulatory Class	Class II	Same	None
Regulation Number	21 C.F.R. 876.5980	Same	None
Regulation Name	Gastroenterology-Urology	Same	None

Feature	Predicate Device Gastric Balloon Suction Catheter K002838	Subject Device Calibration Tube	Effect on Substantial Equivalence
Indications for Use	The Gastric Balloon Suction Catheter is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch.	Same The LAP-BAND® System Calibration Tube is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch.	None
Outer Diameter	OD = 0.38” + 0.00” / - 0.12”	Same	None
Working Length	23.29” +/- 0.50”	24.73” +/- 0.52”	No impact to substantial equivalence. The additional 1.23” is due to the presence of the distal tip (see Distal Tip feature below). The addition of the distal tip does not affect risk.
Tubing	Dual lumen	Same	None
Distal Side Holes	3 aspiration holes proximal to the balloon to ensure a steady vacuum	Same	None

Feature	Predicate Device Gastric Balloon Suction Catheter K002838	Subject Device Calibration Tube	Effect on Substantial Equivalence
Distal Tip	None	Includes a tip distal to the balloon with 12 aspiration holes.	No impact to substantial equivalence. Tip aids in tracking through the anatomy and the holes minimize the potential for blockage. The addition of the distal tip does not affect risk.
Connector for Suction	The catheter includes an adapter for room suction	Same	None
Balloon + Inflation Valve	The balloon has an inflation capacity ≥ 100 cc min. The catheter is attached to a 6-inch tubing with a stopcock for filling the balloon.	Same	None
Tubing Material	Silicone	Same	None
Markings	Indication marks at 30, 35, 40, 45, and 50 centimeters.	Same	None
Sterility	non-sterile, disposable, single patient use	Same	None
Shelf Life	None.	7 years	None.

VI. PERFORMANCE DATA

Comparative performance testing was conducted to demonstrate that the technological differences between the Lap-Band® System Calibration Tube and the predicate device (Gastric Balloon Suction Catheter, K002838) do not raise concerns of substantial equivalence.

Performance Testing - Bench

Refer to **Table 2** below for a summary of the performance testing performed on the Lap-Band® System Calibration Tube.

Table 2: Summary of Non-Clinical Bench Testing for the Subject Device

Test Performed	Acceptance Criteria	Results
Burst Test of Calibration Tube Balloon	The balloon must remain intact while inflated to four (4) times its recommend fill volume (25cc x 4 = 100cc).	**Pass**
Sensor Tip Force to Pull	The sensor tip (distal tip) must be 1.5 times greater than the acceptance criteria of the calibration balloon pull (1.5 x 13 = 19.5lbf).	**Pass**
Force to Remove StopCock	The stopcock must withstand a force of 1 lbf.	**Pass**
Pull Force of Bushing	The bushing must withstand a force of 1 lbf.	**Pass**
Pull force of Fill Tube	The fill tube adhesive joint must withstand a force of 1 lbf.	**Pass**
Adhesive Strength Balloon Pull	The balloon must withstand 13 lbf.	**Pass**
End Connector Pull Force	The end connector must withstand 6 lbf.	**Pass**
Hybrid Calibration Tube Suction Functional Testing	Hybrid calibration tube must remove all of the saline in glass beaker within 1 minute.	**Pass**
Pull Force Fill Tube / Over-Mold Testing	The fill tube or over-mold joint must withstand a force of 1 lb. This component's only function is to provide a path for inflation of the balloon.	**Pass**
Pull Force of Proximal Tubing / Over-Mold Testing	The proximal tubing or over-mold joint must withstand a force of 1 lb.	**Pass**

Biocompatibility Testing

Refer to **Table 3** below for a summary of the biocompatibility testing performed on Lap-Band® System Calibration Tube.

Table 3: Biocompatibility Testing Summary – Subject Device

Biocompatibility Test	Acceptance Criteria	Results
Cytotoxicity Study Using the ISO Elution Method	Observations for test and negative control at 24, 48 and 72 hours. Presence or absence of a confluent monolayer, vacuolization, cellular swelling and crenation and the percentage of cellular lysis are recorded. Scoring was nontoxic, intermediate, or toxic.	The CTE Score was N (non-toxic at 24, 48 and 72 hours).
ISO Sensitization Study in the Guinea Pig	The response, pattern, character, and duration of any test animal reactions are compared to any reactions in the controls. Any dermal inflammatory response at the test sites greater than that seen in any control condition is considered evidence of a potential allergic response.	No evidence of delayed dermal contact sensitization was observed.
ISO Vaginal Irritation Study in the Rabbit	Each animal was observed daily for general health and external signs of irritation around the opening of the vaginal vestibule. After euthanization, tissue sections were evaluated. Macroscopic reactions were compared between test and control animals. Microscopic evaluation scores for all SC test animals were added together and divided by the number of test animals to obtain the SC average. The CSO averages were similarly calculated. The Irritation Index was scored from zero to 16, with zero as nonirritant and 16 severe irritant.	The microscopic SC and CSO extracts were a nonirritant.

VII. CONCLUSION

ReShape Lifesciences concludes, through a review of the non-clinical assessments, the comparison of the device classification, indications for use, operating principle, technological characteristics, and biocompatibility that the subject device, the Lap-Band® System Calibration Tube, is substantially equivalent to the predicate device, the Gastric Balloon Suction Catheter (K002838). Any differences between the subject device and the predicate device do not raise different questions of safety and effectiveness.